

INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 701/PTO 15 APR 2005)

10/531466

Applicant's or agent's file reference 12054875-GIB	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/IT 03/00777	International filing date (day/month/year) 25.11.2003	Priority date (day/month/year) 25.11.2002
International Patent Classification (IPC) or both national classification and IPC A61M25/00		
Applicant INVATEC S.R.L. et al.		

1. This International preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
 - ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 2 sheets.
3. This report contains indications relating to the following items:
 - I Basis of the opinion
 - II Priority
 - III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV Lack of unity of invention
 - V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI Certain documents cited
 - VII Certain defects in the international application
 - VIII Certain observations on the international application

Date of submission of the demand 25.05.2004	Date of completion of this report 22.02.2005
Name and mailing address of the International preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Cuiper, R Telephone No. +49 89 2399-2419



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I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-8 as originally filed

Claims, Numbers

1-16 filed with telefax on 27.01.2005

Drawings, Sheets

1/8-8/8 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages:
- the claims, Nos.:
- the drawings, sheets:

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5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	11,12,14
	No: Claims	1-10, 13, 15-16
Inventive step (IS)	Yes: Claims	
	No: Claims	1-16
Industrial applicability (IA)	Yes: Claims	
	No: Claims	1-16

2. Citations and explanations

see separate sheet

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Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

- D1: EP-A-0 778 040 (SARCOS INC) 11 June 1997 (1997-06-11)
- D2: GB-A-2 319 183 (SMITHS INDUSTRIES PLC) 20 May 1998 (1998-05-20)
- D3: WO 97/25914 A (BOSTON SCIENT CORP) 24 July 1997 (1997-07-24)
- D4: EP-A-0 937 481 (PRECISION VASCULAR SYSTEMS INC) 25 August 1999 (1999-08-25)
- D5: EP-A-0 215 173 (WARNER LAMBERT TECH) 25 March 1987 (1987-03-25)

(1) The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

The document D3 discloses (the references in parentheses applying to this document):

Tube (fig. 2) comprising in at least one portion of its wall notches with width A such as to locally increase the flexibility of the tube, said notches being provided in at least one distal zone of said tube (p. 9, l. 9) and exhibiting a substantially discontinuous helical pattern (p. 9, l. 13-16), wherein said notches form an angle α with a circumference obtained on the outside surface of said tube (p. 9, l. 19, angle θ), said angle α having increasing measure from the distal end in proximal direction (angle θ_1 at the proximal side is greater than angle θ_2 at the distal side, p. 9, l. 29-32),

Thus, the subject-matter of the claim is known from D3.

The notch can not be seen as continuous since on p. 9 of D3 it is stated that "a portion of slot 32 may be replaced with a grooved section [...] which is only partially cut through the wall of distal tubular portion" which is interpreted as discontinuation of the pattern.

(2) Dependent claims 2-16 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, see documents D3, D1, D2, D4 and the

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corresponding passages cited in the search report.

2 Other objections

- Independent claim 1 is not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D3) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
- Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1-D5 is not mentioned in the description, nor are these documents identified therein.

CLAIMS

1. Tube, in particular for the use in medical devices in the form of catheters for endoluminal operations, comprising in at least one portion (13) of its wall (11) notches (14) with width A such as to locally increase the flexibility of the tube, said notches (14) being provided in at least one distal zone of said tube and exhibiting a substantially discontinuous helical pattern, wherein said notches form an angle α with a circumference obtained on the outside surface of said tube, said angle α having increasing measure from the distal end in proximal direction.
2. Tube according to claim 1, comprising a plurality of notches having a predetermined axial distance from one another.
3. Tube according to claim 2, wherein said axial distance between said notches increases from the distal end in proximal direction.
4. Tube according to claim 1, wherein said width of said angle α increases by an amount β at each arc γ covered on the surface of the tube in terms of width E of each notch and of angular distance G between two consecutive notches.
5. Tube according to claim 4, wherein the measure of said arc γ is comprised between 0° and 360° .
6. Tube according to any one of the previous claims, wherein said notches have a width comprised between $5 \mu\text{m}$ and 1 mm .
7. Tube according to any one of the previous claims, wherein

said notches have a width comprised between 10 μm and 25 μm .

8. Tube according to any one of the previous claims, wherein at least one of the ends, said notches comprise a circular hole having a larger diameter than the notch width.
9. Tube according to any one of the previous claims, wherein the portion comprising said notches extends from the distal end in proximal direction for a length comprised between 70 and 110 mm.
10. Tube according to any one of the previous claims, wherein the portion comprising said notches extends from the distal end in proximal direction for a length comprised between 80 and 100 mm.
11. Tube according to any one of the previous claims, wherein said tube is realised with a metal material.
12. Tube according to any one of the previous claims, wherein said metal material is stainless steel.
13. Tube according to any one of claims from 1 to 13, wherein said tube is made of a polymeric material.
14. Tube according to any one of claims from 1 to 13, wherein said tube is made of a composite material.
15. Tube according to any one of the previous claims, wherein the surface of said tube is covered with a layer of polytetrafluoroethylene (PTFE).
16. Catheter for endoluminal operations comprising a tube according to any one of the previous claims.